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Dated: November 26, 2008

Electronic Signature for Jill Gorny Sloper: /Jill Gorny Sloper/

Docket No.: CDJ-166CPRCE2  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:

Yashwant M. Deo *et al.*

Application No.: 10/035,637

Confirmation No.: 4452

Filed: November 7, 2001

Art Unit: 1644

For: MOLECULAR CONJUGATES COMPRISING  
HUMAN MONOCLONAL ANTIBODIES TO  
DENDRITIC CELLS (as amended)

Examiner: Ewoldt, Gerald R.

MS Patent Extension  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**STATEMENT UNDER 37 CFR § 1.702(b)(2)**

Dear Sir:

1. This statement is respectfully submitted in support of the "Application for Patent Term Adjustment Including Request for Reconsideration Under 37 CFR §1.705(b)" for the above-referenced application. In view of the following, it is respectfully requested that Applicants be granted a minimum patent term adjustment of **472 days**, with an additional term to be added based on the number of days following payment of the issue fee to the date of issuance of a patent for the above-referenced application.

2. The patent term adjustment on the Determination of Patent Term Adjustment Under 35 U.S.C. §154(b) ("Determination") that was attached to the Notice of Allowance is 0 days (a copy of the Determination is submitted herewith as Exhibit A). A copy of the PTO's Patent Term Adjustment calculation ("PTA Sheet") available on Private Pair is also submitted herewith as Exhibit B. Applicants respectfully submit that the determination of 0 days of patent term adjustment is incorrect for the reasons discussed below.

3. The factual bases for the above adjustment are set forth as follows:

**A. Examination Delays Pursuant to 37 CFR §1.702 and §1.703**

Pursuant to 37 CFR §1.703(f), the period of adjustment of the term of the patent under §1.702 is the sum of the periods of examination delay calculated under subparagraphs (a)-(e), to the extent that such periods are not overlapping, less the sum of the periods calculated under §1.704 (the period of Applicant Delay). In the above-referenced application, Applicants are entitled to a period of examination delay equal to the sum of the periods of delay under §1.703(a) and (b) for the reasons set forth below.

(i) “14 Month Delay” Pursuant to §1.703(a)(1)

In accordance 37 CFR §1.703(a)(1), Applicants are entitled to a period of patent term adjustment due to the failure by the Office to mail an action under 35 U.S.C. §132 not later than 14 months after the actual filing date (*i.e.*, by January 7, 2003). As shown in the PTO's Patent Term Adjustment calculation (Exhibit B), the Office failed to mail an action under 35 U.S.C. §132 (a Restriction Requirement) until March 16, 2004. As such, Applicants are entitled to a period of patent term adjustment beginning January 8, 2003 and ending on March 16, 2004, the date of mailing of the Restriction Requirement by the Office. Accordingly, the period of patent term adjustment due to the 14 Month Delay by the Office is 434 days. This is consistent with the PTA Sheet (Exhibit B) from the Office.

(ii) “Three Years Delay” Pursuant to 37 CFR §1.703(b)

It is anticipated that the Office will not comply with the requirement of 35 U.S.C. §154(b) and 37 CFR §1.702(b), which requires issuance of a patent within 3 years after the date on which the application was filed under 35 U.S.C. §111(a). As indicated in the Notice of Allowance, a patent is projected to issue on April 14, 2009. As such, there is an anticipated delay of 1619 days.

However, since the exclusionary period for continued examination set forth in 37 CFR §1.702(b)(1) applies to the instant patent, the number of days in the period beginning on the date on which Patentees first filed a Request for Continued Examination (March 30, 2006) and ending on the future issue date of a corresponding patent (April 14, 2009), *i.e.*, 1112 days, is excluded from the period of Three Years Delay (*i.e.*, 1619 days). Therefore, in accordance with 37 CFR §1.703, Patentees have calculated a maximum period of Three Years Delay based on the

period of time beginning on the day after the date that is three years after the date on which the above-referenced patent was filed under 35 U.S.C. § 111(a) (*i.e.*, November 8, 2004), and ending on the date Patentees first filed a Request for Continued Examination (*i.e.*, March 30, 2006).

This period of delay is 507 days.

Additionally, Applicants respectfully note that a Notice of Appeal was filed on January 30, 2006. Pursuant to 37 CFR 1.702(b)(4) the requirement that the Office must issue a patent within 3 years after the date on which the application was filed under 35 U.S.C. §111(a) does not include the period of appellate review by the BPAI or a Federal Court. However, as the Notice of Appeal that was filed on January 30, 2006 was effectively withdrawn by the subsequent Request for Reconsideration that was filed on March 30, 2006, the Exclusion for Appellate Review does not affect the present calculation.

In sum, the minimum period of examination delay of 507 days is to be extended by an additional term equal to the number of days following payment of the issue fee on to the date of issuance of a patent.

(iii) “4 Month PTO Response to Applicant Reply” Pursuant to 37 CFR 1.702(a)(2)

Applicants respectfully submit that an additional period of examination delay of 113 days accrued for the failure of the Office to issue a reply within four months, as required by 37 CFR 1.702(a)(2). Specifically, the Office did not respond to Applicants' Response to Restriction Requirement (dated April 16, 2004) until December 7, 2004, *i.e.*, 113 days after a response was required under 37 CFR 1.702(a)(2). This period is not shown on Exhibit B, the PTA Sheet from the Office. Instead, the Office incorrectly calculated the examination delay under 37 CFR 1.702(a)(2) as beginning four months after Applicants' Response to a Notice to Comply with Sequence Requirements (dated July 29, 2004), *i.e.*, a delay of 8 days, rather than four months after Applicants' Response to Restriction Requirement, *i.e.*, a delay of 113 days. Pursuant to 37 CFR §1.702(a)(2), the correct period of examination delay is 113 days and this period should be added to the period of delay by the Office.

(iv) Calculation of Total Period of Examination Delay Pursuant to 37 CFR §1.703(f)

As set forth in 37 CFR §1.703(f), the period of examination delay based on the grounds set forth in 37 CFR §1.702 is the sum of the period of 14 Month Delay (434 days), the minimum period of Three Years Delay (507 days) and the 4 Month PTO Response to Applicant Delay

(113), or 1054 days, to the extent these periods of delay are not overlapping. As the period of 14 Month Delay ended on March 16, 2004, prior to the first day of the period of Three Years Delay, *i.e.*, November 7, 2004, Applicants submit that these periods are not overlapping. However, the period of the 4 Month PTO Response to Applicant Delay and the Three Year Delay overlap between November 7, 2004 through December 7, 2004, *i.e.*, by 30 days. Accordingly, the sum of the total examination delays (1054) is reduced by the period of overlap (30 days), resulting in a total examination delay of 1024 days.

**B. “Applicant Delay” Pursuant to 37 CFR §1.704**

Pursuant to 37 CFR §1.704 the period of adjustment of the term of the patent due to examination delay is reduced by the period of Applicant Delay. As shown in the PTO’s Patent Term Adjustment calculation (Exhibit B), the Office has calculated a period of Applicant Delay of 448 days. Applicants respectfully submit that the correct period of Applicant Delay is 552 days and seek correction based on the following remarks.

**(i) Applicant Delay for Filing an Information Disclosure Statement**

Applicants respectfully submit that an additional period of Applicant Delay of 104 days accrued for the delayed submission of an Information Disclosure Statement (IDS) on July 29, 2004. This IDS was filed without a statement under 37 CFR §1.704(d), 104 days after the filing of a response by Applicants to the Restriction Requirement on March 16, 2004. This period is not shown on Exhibit B, the PTA Sheet from the Office. Pursuant to 37 CFR §1.704(c)(8), this 104 day period should be considered an Applicant Delay and should be added to the period of delay by Applicants.

**(ii) Applicant Delay for Responding to Non-Final Action Dated December 7, 2004**

Applicants respectfully submit that an additional period of Applicant Delay of 64 days accrued for the delayed submission of an Amendment and Response on May 10, 2005. This is consistent with the PTA Sheet (Exhibit B) from the Office. Accordingly, pursuant to 37 CFR §1.704(b), this 64 day period should be considered an Applicant Delay and should be added to the period of delay by Applicants.

**(iii) Applicant Delay for Responding to Final Action Dated July 29, 2005**

Applicants respectfully submit that an additional period of Applicant Delay of **93 days** accrued for the delayed filing of a Notice of Appeal on January 30, 2006. This is consistent with the PTA Sheet (Exhibit B) from the Office. Accordingly, pursuant to 37 CFR §1.704(b), this 93 day period should be considered an Applicant Delay and should be added to the period of delay by Applicants.

(iv) Applicant Delay for Responding to Final Action Dated May 23, 2006

Applicants respectfully submit that an additional period of Applicant Delay of **91 days** accrued for the delayed submission of an Amendment and Response on November 22, 2006. This is consistent with the PTA Sheet (Exhibit B) from the Office. Accordingly, pursuant to 37 CFR §1.704(b), this 91 day period should be considered an Applicant Delay and should be added to the period of delay by Applicants.

(v) Reply Having Omission

Applicants respectfully submit that an additional period of Applicant Delay of **86 days** accrued for the submission of a Non-Responsive Amendment on November 22, 2006. This Non-Responsive Amendment is considered a “reply having an omission.” Therefore, pursuant to 37 CFR §1.704(c)(7), the period of adjustment shall be reduced by the number of days beginning on the day after the date the reply having an omission was filed (*i.e.*, November 23, 2006) and ending on the date that the reply correcting the omission was filed (*i.e.*, February 16, 2007), or 86 days. This is consistent with the PTA Sheet (Exhibit B) from the Office. Accordingly, this 86 day period should be considered an Applicant Delay and should be added to the period of delay by Applicants.

(vi) Applicant Delay for Responding to Final Action Dated May 9, 2007

Applicants respectfully submit that an additional period of Applicant Delay of **76 days** accrued for the delayed filing of a Request for Continued Examination on October 24, 2007. This is consistent with the PTA Sheet (Exhibit B) from the Office. Accordingly, pursuant to 37 CFR §1.704(b), this 76 day period should be considered an Applicant Delay and should be added to the period of delay by Applicants.

(vii) Applicant Delay for Filing an Information Disclosure Statement

Applicants respectfully submit that an additional period of Applicant Delay of **38 days** accrued for the delayed submission of an Information Disclosure Statement (IDS) on April 23, 2008, which was filed without a statement under 37 CFR §1.704(d). This is consistent with the PTA Sheet (Exhibit B) from the Office. Pursuant to 37 CFR §1.704(c)(8), this 38 day period should be considered an Applicant Delay and should be added to the period of delay by Applicants.

(viii) Calculation of the Total Period of Applicant Delay

In view of the above, Applicants have calculated a total period of Applicant Delay of **552 days** which is the sum of the following Applicant Delays: (i) the 104 day period; (ii) the 64 day period ; (iii) the 93 day period; (iii) the 91 day period ; (iv) the 86 day period; (v) the 76 day period; and (vi) the 38 day period. Applicants respectfully submit that the correct period of Applicant Delay is **552 days, not 448 days**, and request appropriate correction by the Office.

C. Calculation of Correct Patent Term Adjustment Pursuant to 37 CFR §1.702(f)

As set forth in 37 CFR §1.703(f), Applicants are entitled to a period of patent term adjustment equal to the period of examination delays reduced by the period of Applicant Delay. Therefore, Applicants submit that the correct patent term adjustment for the above-referenced application is **at least 472 days**, which is the difference between the total period of examination delay (1024 days) and the period of Applicant Delay (552 days). Applicants further submit that the term of 472 days should be extended by an additional term equal to the number of days following payment of the issue fee to the date of issuance of a patent for the above-referenced application in accordance with 37 CFR §1.703(b). **As such, the correct patent term adjustment upon issuance of a patent is expected to be the sum of 472 days (as calculated herein) and the number of days from payment of the issue fee to issuance of a patent.**

4. In accordance with 37 CFR§1.705(b)(2)(iii), Applicants submit that the pending patent corresponding to this application is subject to a terminal disclaimer over any patent issuing from U.S. Patent Application No.: 10/903191, entitled "Antibody Vaccine Conjugates and Uses Therefor."

In view of the foregoing, it is respectfully requested that this Application for Patent Term Adjustment be favorably considered and that a corrected Determination of Patent Term Adjustment be issued to reflect a minimum patent term adjustment of 472 days, with an additional term to be added based on the number of days following payment of the issue fee to the date of issuance of a patent for the above-referenced application.

Dated: November 26, 2008

Respectfully submitted,

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